



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| (51) International Patent Classification ⁶ : A23G 3/30 | A1 | (11) International Publication Number: WO 98/23165 (43) International Publication Date: 4 June 1998 (04.06.98) |
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| (54) Title: METHOD OF CONTROLLING RELEASE OF CAFFEINE IN CHEWING GUM AND GUM PRODUCED THEREBY (57) Abstract <p>A method for producing a chewing gum with a controlled release of caffeine, as well as the chewing gum so produced, is obtained by physically modifying caffeine's properties by coating and drying. Caffeine is coated by encapsulation, partially coated by agglomeration, entrapped by absorption, or treated by multiple steps of encapsulation, agglomeration, and absorption. The coated caffeine is then co-dried and particle sized to produce a release-modified caffeine. When incorporated into the chewing gum, these particles are adapted to produce a fast release or a delayed release when the gum is chewed.</p> | | |

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METHOD OF CONTROLLING RELEASE OF
CAFFEINE IN CHEWING GUM AND
GUM PRODUCED THEREBY

5 BACKGROUND OF THE INVENTION

The present invention relates to methods for producing chewing gum. More particularly the invention relates to producing chewing gum containing a high amount of stimulant known as
10 caffeine. The caffeine that is added to the chewing gum has been treated to control its rate of release in chewing gum.

In recent years, efforts have been devoted to controlling release characteristics of various
15 ingredients in chewing gum. Most notably, attempts have been made to delay the release of sweeteners and flavors in various chewing gum formulations to thereby lengthen the satisfactory chewing time of the gum. Delaying the release of sweeteners and
20 flavors can also avoid an undesirable overpowering burst of sweetness or flavor during the initial chewing period. On the other hand, some ingredients have been treated so as to increase their rate of release in chewing gum.

Besides sweeteners, other ingredients may require a controlled release from chewing gum. Stimulants such as caffeine may be added to gum; however, stimulants are not generally released very readily. Caffeine may be encapsulated in a water
30 soluble matrix such that, during the chewing period, the caffeine may be released quickly resulting in a fast release of stimulant as in a beverage. This would allow chewing gum to be a carrier for caffeine and, with its fast release, to be an effective
35 stimulant.

On the other hand, serious taste problems may arise because of the bitter nature of caffeine. Thus, a prolonged or delayed release of caffeine would allow for the use of caffeine in gum, but the
40 low level of release may keep the level below its

taste threshold and not give chewing gum a bitter taste quality. Also, slow release may allow some individuals to more easily tolerate caffeine and not cause gastro-intestinal distress.

5 Thus, there are specific advantages to adding caffeine to chewing gum by controlled release mechanisms.

Caffeine use in chewing gum was disclosed in U.S. Patent No. 1,298,670.

10 Chewing gum containing caffeine as a stimulant and to combat fatigue and migraine headaches is disclosed in French Patent No. 2,345,938 and in West Germany Patent No. 4,342,568.

15 Also, two Japanese Patent Publications, Nos. JP 91-112450 and JP 91-251533, disclose use of caffeine in chewing gum to reduce drowsiness.

 In Japanese Patent Publication No. JP 96-019370, caffeine is added to chewing gum as an after
20 meal chewing gum to replace tooth brushing.

Caffeine is a well known stimulant from coffee and tea, and several patents disclose use of coffee or tea in gum, such as Japanese Patent Publication No. JP 94-303911, South Korea Patent
25 Publication No. 94-002868, and PCT Patent Publication No. WO 95-000038.

SUMMARY OF THE INVENTION

 The present invention is a method of
30 producing chewing gum with physically modified caffeine to control its release. The present invention also relates to the chewing gum so produced. Caffeine may be added to sucrose type gum formulations, replacing a small quantity of sucrose.
35 The formulation may be a low or high moisture formulation containing low or high amounts of moisture containing syrup. Caffeine may also be used in low or non-sugar gum formulations, replacing a small quantity of sorbitol, mannitol, other

polyols or carbohydrates. Non-sugar formulations may include low or high moisture sugar free chewing gums.

Caffeine may be combined or codried with bulk sweeteners for use in chewing gum including sucrose, dextrose, fructose and maltodextrins, as well as sugar alcohols such as sorbitol, mannitol, xylitol, maltitol, lactitol, hydrogenated isomaltulose and hydrogenated starch hydrolyzates.

5 The modified release rate noted above may be a fast release or a delayed release. The modified release of caffeine is obtained by encapsulation, partial encapsulation or partial coating, entrapment or absorption with high or low
10 water soluble materials or water insoluble materials. The procedures for modifying the caffeine include spray drying, spray chilling, fluid bed coating, coacervation, extrusion and other agglomerating and standard encapsulating techniques.
15 Caffeine may also be absorbed onto an inert or water-insoluble material. Caffeine may be modified in a multiple step process comprising any of the processes or a combination of the processes noted. Prior to encapsulation, caffeine may also be
20 combined with bulk sweeteners including sucrose, dextrose, fructose, maltodextrin or other bulk sweeteners, as well as sugar alcohols such as sorbitol, mannitol, xylitol, maltitol, lactitol, hydrogenated isomaltulose, and hydrogenated starch
25 hydrolyzates.
30

Prior to encapsulation, caffeine may be combined with high-intensity sweeteners, including but not limited to thaumatin, aspartame, alitame, acesulfame K, saccharin acid and its salts, glycyrrhizin, cyclamate and its salts, stevioside
35 and dihydrochalcones. Co-encapsulation of caffeine along with a high-intensity sweetener may reduce the bitterness of caffeine and control the sweetener release with caffeine. This can improve the quality

of the gum product and increase consumer acceptability.

In addition to use of high-intensity sweeteners, bitterness inhibitors such as sodium gluconate, sodium ascorbate or other sodium salts may be combined with caffeine prior to encapsulation to reduce the overall bitterness caused by caffeine and result in a gum product having increased consumer acceptability.

10

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Caffeine is a natural chemical found in a variety of food products such as coffee, tea, cocoa, chocolate, and various other beverages. Caffeine is known as an effective stimulant to increase energy and reduce drowsiness. Caffeine has a naturally bitter taste. The bitterness, however, actually improves the flavor perception of some beverages such as coffee and carbonated beverages.

20

When caffeine is added to chewing gum at a level of about 0.2% to about 5%, caffeine imparts an intense bitterness to the chewing gum that lasts throughout the chewing period. The higher the level used, the stronger the bitterness. At about 0.2%, which is about 5 mg per 2.7 gram stick, the bitterness is below the threshold limit and is not readily discernible. Taste limits in chewing gum are generally about 0.4% (10 mg) to about 4% (100 mg) in a stick of gum. The 60-80 mg level of caffeine is about the level of caffeine found in a conventional cup of coffee. The target level of caffeine in stick gum is about 40 mg per stick, with a range of about 25-60 mg, so that a five stick package of gum would contain about 200 mg of caffeine, or the equivalent of caffeine in two strong cups of coffee. However, at this level caffeine bitterness overwhelms the flavor initially and lasts throughout the chewing period.

35

With the caffeine release modified to result in a fast release of caffeine with the chewing gum solubles and sweeteners, the bitterness can be effectively reduced. If high-intensity sweeteners can be blended with caffeine to release at the same time, this too can reduce the bitterness effect. Other chemicals that inhibit bitterness may be blended with caffeine to also reduce bitterness.

Caffeine is not a highly water soluble substance and, therefore, has a moderately slow release from chewing gum. Caffeine is 2.1% soluble in water at room temperature, 15% soluble in water at 80°C and 40% soluble in boiling water. This gives caffeine a moderately slow release as shown below:

| <u>Chewing Time</u> | <u>% Caffeine Release</u> |
|---------------------|---------------------------|
| 0 min | -- |
| 5 min | 56 |
| 10 min | 73 |
| 20 min | 88 |
| 40 min | 97 |

Generally, highly water soluble ingredients are about 80-90% released after only five minutes of chewing. For caffeine, only about 50% is released, while the other 50% remains in the gum after five minutes of chewing. After 20 minutes almost 90% of caffeine is released.

Even if caffeine is dissolved in hot water and mixed in the gum, when the gum is cooled or kept at room temperature, caffeine may return to its normal crystalline state and release at the same rate as shown above.

Caffeine salt compounds such as caffeine citrate, caffeine sodium benzoate, caffeine sodium salicylate, which may be more water soluble and less bitter than caffeine, may also be encapsulated or

entrapped for controlled release in accordance with the present invention.

Caffeine can be added to chewing gum as a powder, as an aqueous dispersion, or dispersed in glycerin, propylene glycol, corn syrup, hydrogenated starch hydrolygate, or any other compatible aqueous dispersion.

For aqueous dispersions, an emulsifier can also be mixed in the solution with the caffeine and the mixture added to a chewing gum. A flavor can also be added to the caffeine/emulsifier mixture. The emulsion formed can be added to chewing gum. Powdered caffeine may also be mixed into a molten chewing gum base during base manufacture or prior to manufacture of the gum. Caffeine may also be mixed with base ingredients during base manufacture.

As stated previously, caffeine releases slowly from chewing gum during the early stages of mastication of the gum because of its low solubility in water. Physical modifications of the caffeine by encapsulation with a highly water soluble substrate will increase its release in chewing gum by increasing the solubility or dissolution rate of caffeine. Any standard technique which gives partial or full encapsulation of the caffeine can be used. These techniques include, but are not limited to, spray drying, spray chilling, fluid-bed coating and coacervation. These encapsulation techniques may be used individually in a single step process or in any combination in a multiple step process. The preferred technique for fast release of caffeine is spray drying.

Caffeine may also be encapsulated or entrapped to give a delayed release from chewing gum. A slow, even release of caffeine can give a reduced bitterness over a long period of time and blend more easily with longer lasting flavors and sweeteners. Caffeine may be encapsulated with sweeteners, specifically high-intensity sweeteners such as

thaumatin, dihydrochalcones, acesulfame K, aspartame, sucralose, alitame, saccharin, and cyclamates. These can also have the effect of reducing bitterness. Additional bitterness inhibitors can also be combined with caffeine and sweeteners to give a reduced bitterness with delayed release caffeine.

The encapsulation techniques described herein are standard coating techniques and generally give varying degrees of coating from partial to full coating, depending on the coating composition used in the process. Generally, compositions that have high organic solubility, good film-forming properties and low water solubility give better delayed release of caffeine, while compositions that have high water solubility give better fast release. Such low water-solubility compositions include acrylic polymers and copolymers, carboxyvinyl polymer, polyamides, polystyrene, polyvinyl acetate, polyvinyl acetate phthalate, polyvinylpyrrolidone and waxes. Although all of these materials are possible for encapsulation of caffeine sweetener, only food-grade materials should be considered. Two standard food-grade coating materials that are good film formers but not water soluble are shellac and Zein. Others which are more water soluble, but good film formers, are materials like agar, alginates, a wide range of cellulose derivatives like ethyl cellulose, methyl cellulose, sodium hydroxymethyl cellulose, and hydroxypropylmethyl cellulose, dextrin, gelatin, and modified starches. These ingredients, which are generally approved for food use, may give a fast release when used as an encapsulant for caffeine. Other encapsulants like acacia or maltodextrin can also encapsulate caffeine and give a fast release rate of caffeine in gum.

The amount of coating or encapsulating material on the caffeine may also control the length of time for its release from chewing gum.

Generally, the higher the level of coating and the lower amount of active caffeine, the slower the release during mastication with low water soluble compositions. The release rate is generally not
5 instantaneous, but gradual over an extended period of time. To obtain the delayed release to blend with a gum's flavor release, the encapsulant should be a minimum of about 20% of the coated caffeine. Preferably, the encapsulant should be a minimum of
10 about 30% of the coated caffeine, and most preferably should be a minimum of about 40% of the coated caffeine. Depending on the coating material, a higher or lower amount of coating material may be needed to give the desired release.

15 Another method of giving a modified release of caffeine is agglomeration with an agglomerating agent which partially coats caffeine. This method includes the step of mixing caffeine and an agglomerating agent with a small amount of water
20 or solvent. The mixture is prepared in such a way as to have individual wet particles in contact with each other so that a partial coating can be applied. After the water or solvent is removed, the mixture is ground and used as a powdered, coated caffeine.

25 Materials that can be used as the agglomerating agent are the same as those used in encapsulation mentioned previously. However, since the coating is only a partial encapsulation and caffeine is not very water soluble, some
30 agglomerating agents are more effective in increasing caffeine release than others. Some of the better agglomerating agents for delayed release are the organic polymers like acrylic polymers and copolymers, polyvinyl acetate, polyvinylpyrrolidone,
35 waxes, shellac and Zein. Other agglomerating agents are not as effective in giving a delayed release as are the polymers, waxes, shellac and Zein, but can be used to give some delayed release. Other agglomerating agents that give a fast release

include, but are not limited to, agar, alginates, a wide range of water soluble cellulose derivatives like ethyl cellulose, methyl cellulose, sodium hydroxymethyl cellulose, hydroxypropylmethyl
5 cellulose, dextrin, gelatin, modified starches, and vegetable gums like guar gum, locust bean gum and carrageenin. Even though the agglomerated caffeine is only partially coated, when the quantity of coating is increased compared to the quantity of
10 caffeine, the release of caffeine can also be modified for mastication. The level of coating used in the agglomerated product is a minimum of about 5%. Preferably, the coating level is a minimum of about 15% and more preferably about 20%. Depending
15 on the agglomerating agent, a higher or lower amount of agent may be needed to give the desired release of caffeine.

Caffeine may be coated in a two-step process or a multiple step process. Caffeine may be
20 encapsulated with any of the materials as described previously and then the encapsulated caffeine can be agglomerated as previously described to obtain an encapsulated/agglomerated/caffeine product that could be used in chewing gum to give a delayed
25 release of caffeine.

In another embodiment of this invention, caffeine may be absorbed onto another component which is porous and become entrapped in the matrix of the porous component. Common materials used for
30 absorbing caffeine include, but are not limited to, silicas, silicates, pharmasorb clay, spongelike beads or microbeads, amorphous carbonates and hydroxides, including aluminum and calcium lakes, all of which result in a delayed release of
35 caffeine. Other water soluble materials including amorphous sugars such as spray-dried dextrose, sucrose, alditols and vegetable gums and other spray-dried materials result in a faster release of caffeine.

Depending on the type of absorbent materials and how it is prepared, the amount of caffeine that can be loaded onto the absorbent will vary. Generally materials like polymers or
5 spongelike beads or microbeads, amorphous sugars and alditols and amorphous carbonates and hydroxides absorb about 10% to about 40% of the weight of the absorbent. Other materials like silicas and
10 pharماسorb clays may be able to absorb about 20% to about 80% of the weight of the absorbent.

The general procedure for absorbing caffeine onto the absorbent is as follows. An absorbent like fumed silica powder can be mixed in a powder blender and an aqueous solution of caffeine
15 can be sprayed onto the powder as mixing continues. The aqueous solution can be about 1 to 2% solids, and higher solid levels to 15-30% may be used if temperatures up to 90°C are used. Generally water is the solvent, but other solvents like alcohol
20 could also be used if approved for use in food. As the powder mixes, the liquid is sprayed onto the powder. Spraying is stopped before the mix becomes damp. The still free-flowing powder is removed from the mixer and dried to remove the water or other
25 solvent, and is then ground to a specific particle size.

After the caffeine is absorbed or fixed onto an absorbent, the fixative/caffeine can be coated by encapsulation. Either full or partial
30 encapsulation may be used, depending on the coating composition used in the process. Full encapsulation may be obtained by coating with a polymer as in spray drying, spray chilling, fluid-bed coating, coacervation, or any other standard technique. A
35 partial encapsulation or coating can be obtained by agglomeration of the fixative caffeine mixture using any of the materials discussed above.

Another form of encapsulation is by entrapment of an ingredient by fiber extrusion or

fiber spinning into a polymer. Polymers that can be used for extrusion are PVAC, hydroxypropyl cellulose, polyethylene, and other types of plastic polymers. A process of encapsulation by fiber
5 extrusion is disclosed in U.S. Patent No. 4,978,537, which is hereby incorporated by reference. The water insoluble polymer may be preblended with caffeine prior to fiber extrusion, or may be added after the polymer is melted. As the extrudate is
10 extruded, it results in small fibers that are cooled and ground. This type of encapsulation/entrapment generally gives a very long, delayed release of an active ingredient.

The four methods of use to obtain a
15 modified release of caffeine are: (1) encapsulation by spray drying, fluid-bed coating, spray chilling and coacervation to give full or partial encapsulation, (2) agglomeration to give partial encapsulation, (3) fixation or absorption which also
20 gives partial encapsulation, and (4) entrapment into an extruded compound. These four methods, combined in any usable manner which physically isolates caffeine and modifies its dissolvability or modifies the release of caffeine, are included in this
25 invention.

A method of isolating caffeine from other chewing gum ingredients is to add caffeine to the dusting compound of a chewing gum. A rolling or dusting compound may be applied to the surface of
30 chewing gum as it is formed. This rolling or dusting compound serves to reduce sticking of the chewing gum product to machinery as it is formed and as it is wrapped, and sticking of the product to its wrapper after it is wrapped and is being stored.
35 The rolling compound comprises caffeine powder in combination with mannitol, sorbitol, sucrose, starch, calcium carbonate, talc, other orally acceptable substances or a combination thereof. The rolling compound constitutes from about 0.25% to

about 10%, but preferably about 1% to about 3% by weight of the chewing gum composition. The amount of caffeine powder added to the rolling compound is about 0.05% to about 20% of the rolling compound or about 5 ppm to about 2000 ppm of the chewing gum composition. This method of using caffeine powder in the chewing gum allows for a lower usage level of caffeine, gives the caffeine a fast release rate, reduces caffeine bitterness when used with sweeteners and reduces or eliminates any possible reaction of the caffeine with gum base, flavor components, or other components, yielding improved shelf stability.

Another method of isolating caffeine is to use it in the coating/panning of a pellet chewing gum. Pellet or ball gum is prepared as conventional chewing gum, but formed into pellets that are pillow shaped or into balls. The pellets/balls can then be sugar coated or panned by conventional panning techniques to make a unique sugar coated pellet gum. Caffeine is very stable but not highly water soluble and can be easily dispersed in a sugar solution prepared for sugar panning. Caffeine can also be added as a powder blended with other powders often used in some types of conventional panning procedures. Using caffeine isolates it from other gum ingredients and modifies its release rate in chewing gum. Levels of caffeine may be about 100 ppm (0.01%) to about 25,000 ppm (2.5%) in the coating and about 50 ppm (0.005%) to about 10,000 ppm (1%) of the weight of the chewing gum product. The weight of the coating may be about 20% to about 50% of the weight of the finished gum product.

Conventional panning procedures generally coat with sucrose, but recent advances in panning have allowed the use of other carbohydrate materials to be used in the place of sucrose. Some of these components include, but are not limited to, dextrose, maltose, palatinose, xylitol, lactitol,

hydrogenated isomaltulose and other new additols or a combination thereof. These materials may be blended with panning modifiers including, but not limited to, gum arabic, maltodextrins, corn syrup, gelatin, cellulose type materials like carboxymethyl cellulose or hydroxymethyl cellulose, starch and modified starches, vegetable gums like alginates, locust bean gum, guar gum, and gum tragacanth, insoluble carbonates like calcium carbonate or magnesium carbonate and talc. Antitack agents may also be added as panning modifiers which allow for the use of a variety of carbohydrates and sugar alcohols in the development of new panned or coated gum products. Flavors may also be added with the sugar coating and with caffeine to yield unique product characteristics.

Another type of pan coating would also isolate caffeine from the chewing gum ingredients. This technique is referred to as film coating and is more common in pharmaceuticals than in chewing gum, but procedures are similar. A film like shellac, Zein, or cellulose-type material is applied onto a pellet-type product forming a thin film on the surface of the product. The film is applied by mixing the polymer, a plasticizer and a solvent (pigments are optional) and spraying the mixture onto the pellet surface. This is done in conventional type panning equipment, or in more advanced side-vented coating pans. When a solvent like alcohol is used, extra precautions are needed to prevent fires and explosions, and specialized equipment must be used.

Some film polymers can use water as the solvent in film coating. Recent advances in polymer research and in film coating technology eliminates the problem associated with the use of flammable solvents in coating. These advances make it possible to apply aqueous films to a pellet or chewing gum product. Although caffeine is not

highly water soluble, it may be added to this aqueous film solution and applied with the film to the pellet or chewing gum product. The aqueous film, or even the alcohol solvent film, in which
5 caffeine is dispersed may also contain a flavor along with the polymer and plasticizer.

The previously described encapsulated, agglomerated, or absorbed caffeine may readily be incorporated into a chewing gum composition. The
10 remainder of the chewing gum ingredients are noncritical to the present invention. That is, the coated particles of caffeine can be incorporated into conventional chewing gum formulations in a conventional manner. Coated caffeine may be used in
15 a sugar chewing gum or a sugarless chewing gum. The coated caffeine may be used in either regular chewing gum or bubble gum.

In general, a chewing gum composition typically comprises a water-soluble bulk portion, a
20 water-insoluble chewable gum base portion and typically water-insoluble flavoring agents. The water-soluble portion dissipates with a portion of the flavoring agent over a period of time during chewing. The gum base portion is retained in the
25 mouth throughout the chew.

The insoluble gum base generally comprises elastomers, resins, fats and oils, waxes, softeners and inorganic fillers. Elastomers may include polyisobutylene, isobutylene-isoprene copolymer and
30 styrene butadiene rubber, as well as natural latexes such as chicle. Resins include polyvinylacetate and terpene resins. Fats and oils may also be included in the gum base, including tallow, hydrogenated and partially hydrogenated vegetable oils, and cocoa
35 butter. Commonly employed waxes include paraffin, microcrystalline and natural waxes such as beeswax and carnauba. According to the preferred embodiment of the present invention, the insoluble gum base constitutes between about 5% and about 95% by weight

of the gum. More preferably the insoluble gum base comprises between about 10% and about 50% by weight of the gum, and most preferably between about 20% and about 35% by weight of the gum.

5 The gum base typically also includes a filler component. The filler component may be calcium carbonate, magnesium carbonate, talc, dicalcium phosphate or the like. The filler may constitute between about 5% and about 60% by weight
10 of the gum base. Preferably, the filler comprises about 5% to about 50% by weight of the gum base.

Gum bases typically also contain softeners, including glycerol monostearate and glycerol triacetate. Further, gum bases may also
15 contain optional ingredients such as antioxidants, colors, and emulsifiers. The present invention contemplates employing any commercially acceptable gum base.

The water-soluble portion of the chewing
20 gum may further comprise softeners, sweeteners, flavoring agents and combinations thereof. Softeners are added to the chewing gum in order to optimize the chewability and mouth feel of the gum. Softeners, also known in the art as plasticizers or
25 plasticizing agents, generally constitute between about 0.5% and about 15% by weight of the chewing gum. Softeners contemplated by the present invention include glycerin, lecithin and combinations thereof. Further, aqueous sweetener
30 solutions such as those containing sorbitol, hydrogenated starch hydrolyzates, corn syrup and combinations thereof may be used as softeners and binding agents in gum.

As mentioned above, the coated caffeine of
35 the present invention may be used in sugar or sugarless gum formulations. Sugar sweeteners generally include saccharide-containing components commonly known in the chewing gum art which comprise, but are not limited to, sucrose, dextrose,

maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids and the like, alone or in any combination. Sugarless sweeteners include components with sweetening characteristics but which are devoid of the commonly known sugars and comprise, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolyzates, maltitol and the like, alone or in any combination.

Depending on the particular caffeine release profile and shelf-stability needed, the coated caffeine of the present invention can also be used in combination with uncoated high-potency sweeteners or with high-potency sweeteners coated with other materials and by other techniques.

A flavoring agent may also be present in the chewing gum in an amount within the range of from about 0.1% to about 10%, preferably from about 0.5% to about 3%, by weight of the gum. The flavoring agents may comprise essential oils, synthetic flavors, or mixtures thereof including, but not limited to oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, clove oil, oil of wintergreen, anise, and the like. Artificial flavoring components are also contemplated for use in gums of the present invention. Those skilled in the art will recognize that natural and artificial flavoring agents may be combined in any sensorally acceptable blend. All such flavors and flavor blends are contemplated by the present invention.

Optional ingredients such as colors, emulsifiers and pharmaceutical agents may be added to the chewing gum.

In general, chewing gum is manufactured by sequentially adding the various chewing gum ingredients to a commercially available mixer known in the art. After the ingredients have been thoroughly mixed, the gum mass is discharged from

the mixer and shaped into the desired form such as by rolling into sheets and cutting into sticks, extruding into chunks or casting into pellets.

Generally, the ingredients are mixed by first melting the gum base and adding it to the running mixer. The base may also be melted in the mixer itself. Color or emulsifiers may also be added at this time. A softener such as glycerin may also be added at this time, along with syrup and a portion of the bulking agent. Further portions of the bulking agent may then be added to the mixer. A flavoring agent is typically added with the final portion of the bulking agent. The coated caffeine of the present invention is preferably added after the final portion of bulking agent and flavor have been added.

The entire mixing procedure typically takes from five to fifteen minutes, but longer mixing times may sometimes be required. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

Examples

The following examples of the invention and comparative examples are provided by way of explanation and illustration.

The formulas listed in Table 1 comprise various sugar formulas in which caffeine can be added to gum after it is dissolved in various aqueous type solvents.

TABLE 1

(Wt. %)

| | Example 1 | Example 2 | Example 3 | Example 4 | Example 5 | Example 6 |
|------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|
| Sugar | 61.9 | 60.4 | 60.8 | 60.8 | 60.8 | 58.3 |
| Gum Base | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 |
| Glycerin | 1.4 | 1.4 | 0.0 | 0.0 | 0.0 | 1.4 |
| Corn Syrup | 15.9 | 15.9 | 12.9 | 12.9 | 12.9 | - |
| Lecithin | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| Peppermint Flavor | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Liquid/ Caffeine blend | 0.5 | 2.0 | 6.0 | 6.0 | 6.0 | 20.0 |

Example 1 and 2 - Caffeine powder can be
5 added directly to the gum.

Example 3 - A 10.0 g portion of caffeine
can be dissolved in 90.0 g hot water, making a 10.0%
solution, and added to gum.

Example 4 - A 5.0 gram portion of caffeine
10 can be dissolved in 95.0 gram of hot propylene
glycol, making a 5.0% solution, and added to gum.

Example 5 - A 5.0 gram portion of caffeine
can be dissolved in 95.0 gram of hot glycerin,
making a 5.0% solution, and added to gum.

Example 6 - A 2.5 gram portion of caffeine
15 can be dissolved in hot corn syrup, making a 2.5%
solution, and added to gum.

In the next examples of a sugar gum
formulation, caffeine can be dissolved in hot water
20 and emulsifiers can be added to the aqueous
solution. Example solutions can be prepared by
dissolving 10 grams of caffeine in 90 grams hot
water and adding 5 grams of emulsifiers of various
hydrophilic-lipophilic balance (HLB) values to the

solution. The mixtures can then be used in the following formulas.

TABLE 2
(WT. %)

5

| | Exempl e 7 | Exempl e 8 | Exempl e 9 | Exempl e 10 | Exempl e 11 | Exempl e 12 |
|---|------------------|------------------|------------------|-------------------|-------------------|-------------------|
| Sugar | 50.7 | 50.7 | 50.7 | 50.7 | 50.7 | 50.7 |
| Base | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 |
| Corn Syrup | 12.9 | 12.9 | 12.9 | 12.9 | 12.9 | 12.9 |
| Glycerin | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |
| Dextrose Monohydrate | 9.9 | 9.9 | 9.9 | 9.9 | 9.9 | 9.9 |
| Peppermint Flavor | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Caffeine/ Emulsifier Water Mixture | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 |
| | None | HLB=2 | HLB=4 | HLB=6 | HLB=9 | HLB=12 |

Examples 13-18 - The same as the formulations made in Examples 7-12, respectively, except that the flavor can be mixed together with the aqueous caffeine solution and emulsified before adding the mixture to the gum batch.

Caffeine can also be blended into various base ingredients. A typical base formula is as follows:

15

| | <u>Wt. %</u> |
|--------------------------|--------------|
| Polyvinyl acetate | 27 |
| Synthetic rubber | 13 |
| Paraffin Wax | 13 |
| Fat | 3 |
| Glycerol Monostearate | 5 |
| Terpene Resin | 27 |
| Calcium Carbonate Filler | <u>12</u> |
| | 100% |

20

The individual base components can be softened prior to their addition in the base manufacturing process. To the presoftened base component, caffeine can be added and mixed, and then the presoftened base/caffeine blend can be added to make the finished base. In the following examples, caffeine can be mixed first with one of the base ingredients, and the mixed ingredient can then be used in making a base. The ingredients blended with caffeine can then be used at the levels indicated in the typical base formula above.

Example 19 - The terpene resin used to make the base is 98% polyterpene resin and 2% caffeine.

Example 20 - The polyvinyl acetate used to make the base is 98% low M.W. polyvinyl acetate and 2% caffeine.

Example 21 - The paraffin wax used to make the base is 96% paraffin wax and 4% caffeine.

Caffeine may also be added to an otherwise complete gum base.

Example 22 - 0.5% caffeine can be mixed with 99.5% of a gum base having the above listed typical formula. The caffeine can be added near the end of the process after all the other ingredients are added.

The samples of finished base made with caffeine added to different base components can then be evaluated in a sugar-type chewing gum formulated as follows:

TABLE 3

(Wt. %)

(For examples 19, 20, 21, and 22)

| | | |
|----|-------------|------------|
| 5 | Sugar | 55.2 |
| | Base | 19.2 |
| 10 | Corn Syrup | 13.4 |
| | Glycerine | 1.4 |
| | Dextrose | |
| 15 | Monohydrate | 9.9 |
| | Peppermint | |
| | Flavor | <u>0.9</u> |
| 20 | | 100% |

The theoretical level of caffeine in the finished gum is 0.1%.

Using the following formulation of a sugar or sugar-free gum, a variety of encapsulated caffeine samples can be evaluated:

TABLE 4
(Wt. %)

| | <u>Sugar Free</u> | <u>Sugar</u> |
|---|-------------------|--------------|
| Sorbitol | 48.8 | - |
| Sugar | - | 54.7 |
| Mannitol | 8.0 | - |
| Gum Base | 25.5 | 20.0 |
| Glycerin | 8.5 | 1.4 |
| Corn Syrup | - | 12.0 |
| Lycasin brand Hydrogenated Starch Hydrolyzates | 6.8 | - |
| Dextrose Monohydrate | - | 10.0 |
| Peppermint Flavor | 1.4 | 0.9 |
| Active Caffeine | 1.0% | 1.0% |

5

For spray drying, the solids level of an aqueous or alcoholic solution can be about 5-30%, but preferred levels are indicated in the examples listed.

10

Example 23 - An 80% shellac, 20% active sucralose powder mixture is obtained by spray drying an alcohol shellac caffeine solution at total solids of 10%.

15

Example 24 - A 50% shellac, 50% active caffeine powder mixture is obtained by spray drying an appropriate ratio of alcohol/shellac caffeine solution at 10% solids.

20

Example 25 - A 70% Zein, 30% active caffeine powder mixture is obtained by spray drying an alcohol/Zein caffeine solution at 10% solids.

Example 26 - A 40% shellac, 60% active caffeine powder mixture is obtained by fluid-bed

coating caffeine with an alcohol/shellac solution at 30% solids.

Example 27 - A 60% shellac, 40% active caffeine powder mixture is obtained by fluid-bed coating caffeine with an alcohol/shellac solution at 30% solids.

Example 28 - A 40% Zein, 60% active caffeine powder mixture is obtained by fluid-bed coating caffeine with an alcohol/Zein solution at 25% solids.

Example 29 - An 85% wax, 15% active caffeine powder mixture is obtained by spray chilling a mixture of molten wax and caffeine.

Example 30 - A 70% wax, 30% active caffeine powder mixture is obtained by spray chilling a mixture of molten wax and caffeine.

Example 31 - A 70% Zein, 30% active caffeine powder mixture is obtained by spray drying a hot aqueous mixture of caffeine and Zein dispersed in an aqueous, high-pH (pH of 11.6-12.0) media at 10% solids.

Example 32 - A 20% Zein, 80% active caffeine powder mixture is obtained by fluid-bed coating caffeine with an aqueous, high-pH (pH=11.6-12.0) Zein dispersion of 10% solids.

Example 33 - A 20% Zein, 20% shellac, 60% active caffeine powder mixture is obtained by spray drying an alcohol/shellac caffeine mixture and then fluid-bed coating the spray dried product for a second coating of alcohol and Zein.

Examples 23 to 33 would all give nearly complete encapsulation and would delay the release of caffeine sweetener when used in the sugar or sugarless gum formulation in Table 4. The higher levels of coating would give a longer delayed release of sweetener than the lower levels of coating.

Other polymers that are more water soluble and used in coating would have a faster release of the caffeine.

5 Example 34 - An 80% gelatin, 20% active caffeine powder mixture is obtained by spray drying a hot gelatin/caffeine solution at 20% solids.

10 Example 35 - A 30% hydroxypropylmethyl cellulose (HPMC), 70% caffeine powder mixture is obtained by fluid-bed coating caffeine with an aqueous solution of HPMC at 10% solids.

15 Example 36 - A 50% maltodextrin, 50% active caffeine powder mixture is obtained by spray drying a hot aqueous solution of caffeine and maltodextrin at 30% solids.

20 Example 37 - A 40% gum arabic, 60% active caffeine powder mixture is obtained by fluid-bed coating caffeine with an aqueous solution of gum arabic at 30% solids.

25 The coated caffeine from Examples 34 and 35, when used in the chewing gum formula in Table 4, would give a fast release of caffeine. The product coated with maltodextrin and gum arabic in Examples 36 and 37, when used in the gum formula in Table 4, would show very fast release of caffeine in chewing gum compared to caffeine added directly.

Caffeine could also be used in gum as an agglomerated caffeine to give fast or delayed caffeine release. Agglomerated caffeine can be prepared as in the following examples:

30 Example 38 - A 15% hydroxypropylmethyl cellulose (HPMC), 85% active caffeine powder mixture is prepared by agglomerating caffeine and HPMC blended together, with water being added, and the resulting product being dried and ground.

35 Example 39 - A 15% gelatin, 85% active caffeine powder mixture is made by agglomerating caffeine and gelatin blended together, with water being added, and the resulting product being dried and ground.

Example 40 - A 10% Zein, 90% active caffeine powder mixture is made by agglomerating caffeine with an alcohol solution containing 25% Zein, and drying and grinding the resulting product.

5 Example 41 - A 15% shellac, 85% active caffeine powder mixture is made by agglomerating caffeine with an alcohol solution containing 25% shellac, and drying and grinding the resulting product.

10 Example 42 - A 20% HPMC, 80% active caffeine powder mixture is obtained by agglomerating an HPMC and caffeine mixture blended together, with water being added, and the resulting product being dried and ground.

15 Example 43 - A 20% Zein, 80% active caffeine powder mixture is obtained by agglomerating caffeine and Zein dissolved in high-pH water (11.6-12.0) at 15% solids, with the resulting product being dried and ground.

20 Example 44 - A 20% wax, 80% active caffeine powder mixture is obtained by agglomerating caffeine and molten wax, and cooling and grinding the resulting product.

25 Example 45 - A 15% maltodextrin, 85% active caffeine powder mixture is obtained by agglomerating a blend of caffeine and maltodextrin, then adding water, drying and grinding.

All of the above mixtures can be added to any of the following types of chewing gum formulas:

TABLE 5

(Wt. %)

| | <u>Sugar</u> | <u>Sugar With Sorbitol</u> | <u>Sugarles s With Water</u> | <u>Sugarles s With Lycasin</u> | <u>Sugarles s No Water</u> |
|---------------------------------|--------------|----------------------------|------------------------------|--------------------------------|----------------------------|
| Gum Base | 19.2 | 19.2 | 25.5 | 25.5 | 25.5 |
| Sugar | 55.0 | 53.0 | -- | -- | -- |
| Sorbitol | -- | 2.0 | 52.8 | 48.5 | 51.3 |
| Mannitol | -- | -- | 8.0 | 8.0 | 12.0 |
| Corn Syrup | 13.1 | 13.1 | -- | -- | -- |
| Lycasin/ Sorbitol liquid | -- | | 9.5 (a) | 6.8 (b) | -- |
| Glycerin | 1.4 | 1.4 | 1.5 | 8.5 | 8.5 |
| Lecithin | -- | -- | 0.2 | 0.2 | 0.2 |
| Dextrose Monohydrate | 9.9 | 9.9 | -- | -- | -- |
| Flavor | 0.9 | 0.9 | 1.5 | 1.5 | 1.5 |
| Level of Active Sucralose | 0.5 | 0.5 | 1.0 | 1.0 | 1.0 |

5 (a) liquid sorbitol (70% sorbitol, 30% water)

(b) hydrogenated starch hydrolyzate syrup

If each of the examples of agglomerated material (38-45) were evaluated in the formulations shown in Table 5, some samples would give caffeine a delayed release and others a fast release. Samples using Zein, wax, and shellac would yield the slowest release rate, whereas samples with HPMC and gelatin would yield the next slowest release. Maltodextrin would give a fast release compared to caffeine added directly to the gum.

Partially coated or fully coated caffeine can also be used in sugar type gum formulations containing other sugars, such as in the following formulations A-G:

TABLE 6

(Wt. %)

5

| | A | B | C | D | E | F | G |
|--------------------------|------|------|------|------|------|------|------|
| Gum Base | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 | 19.2 |
| Sugar | 58.5 | 49.5 | 48.5 | 48.5 | 49.5 | 51.5 | 51.5 |
| Glycerin | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 | 1.4 |
| Corn Syrup | 19.0 | 23.0 | 19.0 | 19.0 | 23.0 | 16.0 | 16.0 |
| Dextrose | -- | -- | 5.0 | -- | -- | -- | -- |
| Lactose | -- | -- | -- | -- | 5.0 | -- | -- |
| Fructose | -- | -- | 5.0 | -- | -- | -- | -- |
| Invert Sugar | -- | -- | -- | 10.0 | -- | -- | -- |
| Maltose | -- | -- | -- | -- | -- | 10.0 | -- |
| Palatinose | -- | -- | -- | -- | -- | -- | 10.0 |
| Corn Syrup Solids | -- | 5.0 | -- | -- | -- | -- | -- |
| Peppermint Flavor | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 | 0.9 |
| Level of Active Caffeine | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |

These formulations may also contain sugar alcohols such as sorbitol, mannitol, xylitol, lactitol, maltitol, hydrogenated isomaltulose, and Lycasin or combinations thereof. Sugarless type gum formulations with partially coated or fully coated caffeine can also be made using various sugar alcohols, such as the following formulations H-P:

10

TABLE 7

(Wt. %)

| | H | I | J | K | L | M | N | O | P |
|--------------------------------|------|------|------|------|------|------|------|--------------|----------|
| Base | 25.5 | 25.5 | 25.5 | 25.5 | 25.5 | 25.5 | 25.5 | 25.5 | 25.5 |
| Sorbitol | 53.0 | 46.0 | 41.0 | 41.0 | 41.0 | 41.0 | 36.0 | 37.0 | 46.0 |
| Sorbitol Liquid/ Lycasin | 17.0 | 14.0 | 6.0 | -- | 5.0 | -- | -- | 6.0 (a)) | 18.0 (a) |
| Mannitol | -- | 10.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 |
| Maltitol | -- | -- | -- | 5.0 | -- | -- | 5.0 | -- | -- |
| Xylitol | -- | -- | 15.0 | 10.0 | -- | -- | 5.0 | 15.0 | -- |
| Lactitol | -- | -- | -- | -- | 10.0 | -- | -- | -- | -- |
| Palatini | -- | -- | -- | -- | -- | 15.0 | 10.0 | -- | -- |
| t | | | | | | | | | |
| Glycerin | 2.0 | 2.0 | 2.0 | 8.0 | 8.0 | 8.0 | 8.0 | 6.0 | -- |
| Flavor | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Level of Active Caffeine | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |

5

(a) Lycasin, all others use sorbitol liquid

10 All of these formulations in Table 6 and Table 7 which use the agglomerated caffeine as described in the examples (38-45) and in the previous encapsulated examples (23-35) would be expected to give a delayed release of caffeine or a fast release of caffeine compared to a product made by adding caffeine directly to gum as a powder.

15 Multiple step agglomeration/encapsulation procedures can also be used in making release-modified caffeine for use in the formulations in Tables 5, 6 and 7. Examples of multiple step treatments are here described:

20 Example 46 - Caffeine is spray dried with maltodextrin at 30% solids to prepare a powder. This powder is then agglomerated with a hydroxypropylmethyl cellulose (HPMC) in a ratio of 85/15 powder/HPMC, wetted with water and dried.

After grinding the resulting powder will contain about 68% active caffeine, 17% maltodextrin and 15% HPMC.

5 Example 47 - Caffeine is agglomerated with HPMC in a ratio of 85/15 sweetener/HPMC. After drying and grinding, the resulting powder is fluid-bed coated with an alcohol/shellac solution at about 25% solids to give a final product containing about 60% active caffeine, 10% HPMC, and about 30%
10 shellac.

 Example 48 - Caffeine is agglomerated with HPMC in a ratio of 85/15 Sweetener/HPMC. After drying and grinding, the resulting powder is agglomerated with a 15% solids, high-pH, aqueous
15 solution of Zein to give a final product containing about 60% active caffeine, 10% HPMC, and 30% Zein.

 Example 49 - Caffeine is spray dried with a 25% solution of gelatin. The spray dried product is then agglomerated with a 15% solids, high-pH,
20 aqueous solution of Zein. The final product will contain about 50% active caffeine, 20% gelatin, and 30% Zein.

 Example 50 - Caffeine is agglomerated with molten wax in a ratio of 85/15 sweetener/wax. When
25 the mixture cools and is ground, it is fluid-bed coated with a 25% Zein - 75% alcohol solution, giving a final product containing 60% active caffeine, 10% wax and 30% Zein.

 These examples 46-50, when used in any of
30 the formulations noted in Tables 5, 6, and 7 above, give caffeine a delayed release. These multiple step procedures can actually give more delayed release than the single step processes. Multiple step processes of more than two steps may give even
35 longer delayed release times, but may generally become less cost effective and less efficient. Preferably, spray drying can be the first step with additional steps of fluid-bed coating, spray

chilling and agglomeration being part of the latter steps.

For absorption type examples, delayed release rate of caffeine is dependent on the type of absorbing material. Most materials like silicas, silicates, cellulose, carbonates, and hydroxides would be expected to give a more delayed release than amorphous sugar and sugar alcohols. Some examples:

10 Example 51 - A hot 10% solution of caffeine is sprayed onto a precipitated silica to absorb the caffeine. The mixture is dried and coated with a fumed silica. The final product is about 50% active caffeine.

15 Example 52 - A hot 10% solution of caffeine is sprayed onto a pharماسorb clay caffeine. The mixture is dried and ground and gives a final product of about 80% clay and 20% active caffeine.

20 Example 53 - A 10% solution of caffeine is sprayed onto a microcrystalline cellulose powder. The mixture is dried and ground and gives a product that is about 70% microcrystalline cellulose and 30% active caffeine.

25 Example 54 - A 10% solution of caffeine is sprayed onto a high absorption starch. The mixture is dried and ground and gives a product that is about 80% starch and 20% active caffeine.

30 Example 55 - A 10% solution of caffeine is sprayed onto a calcium carbonate powder. The mixture is dried and ground and gives a product of about 90% calcium carbonate and 10% active caffeine.

35 Example 56 - A hot 10% solution of caffeine is sprayed onto a highly absorptive dextrose material. The mixture is dried and ground and gives a product of about 80% dextrose and 20% active caffeine.

 Example 57 - A hot 10% solution of caffeine is sprayed onto a sorbitol powder to absorb the material. The mixture is dried and ground and

gives a product of about 90% sorbitol and 10% active caffeine.

5 The samples prepared in examples 51-57 can be used in gum formulations as noted in Tables 5, 6, and 7. Those preparations which have caffeine absorbed onto a material that is not water soluble are expected to give a delayed release and those that are water soluble are expected to give fast release.

10 Another modification or absorption technique is to dry the caffeine together with a sugar or sugar alcohol, or resolidify the caffeine with sugar or sugar alcohol when mixed together in a molten state.

15 Example 58 - Caffeine is added to molten sorbitol in a ratio of 90 parts sorbitol to 10 parts caffeine. After mixing, the blend is cooled and ground.

20 Example 59 - Caffeine is added to molten dextrose in a ratio of 90 parts dextrose to 10 parts caffeine. After mixing, the blend is cooled and ground.

25 Example 60 - 4% caffeine is dissolved in 96% high fructose corn syrup. The mixture is evaporated to a low moisture and ground.

The product of examples 58-60 may be added to the gum formulations shown in Tables 5, 6 and 7.

30 Many of the examples listed are single step processes. However, more delayed release of the caffeine sweetener may be obtained by combining the various processes of encapsulation, agglomeration, absorption, and entrapment. Any of the preparations made in examples 51-60 can be further treated in fluid-bed coating, spray
35 chilling, or coacervation processes to encapsulate the product, and can be agglomerated with various materials and procedures in a variety of multiple step processes.

The caffeine can also be used with a variety of high-intensity sweeteners and blended together before encapsulation, agglomeration, absorption, and entrapment. This can reduce
5 bitterness associated with caffeine. Some examples are:

Example 61 - Caffeine and aspartame are blended together in a 2/1 ratio as a powder. This mixture is then spray chilled with wax in a ratio of
10 60/40 mixture/wax to obtain a powder containing 40% caffeine, 20% aspartame, and 40% wax.

Example 62 - Caffeine and thaumatin in a 4/1 ratio are dissolved in water with a 10% solution of gelatin and spray dried. This spray dried powder
15 is then agglomerated with a high-pH aqueous 15% Zein solution. The mixture is dried and ground and gives a product containing 40% caffeine, 10% thaumatin, 35% gelatin, and 15% Zein.

Example 63 - Caffeine and alitame in a 7/1 ratio are prepared in a hot 10% solution. This solution is sprayed onto a high absorption silica powder. The mixture is dried, ground and fluid-bed coated with an alcohol/shellac mixture, giving a product that contains 35% caffeine, 5% alitame, 40%
25 silica, and 20% shellac.

Example 64 - Caffeine and sodium cyclamate in a 1/1 ratio are blended together as a powder and then agglomerated with water and hydroxypropylmethyl cellulose (HPMC). This blend is dried, ground and
30 agglomerated further with a high-pH, aqueous 15% solution of Zein to obtain a product containing 34% sodium cyclamate, 34% caffeine, 12% HPMC and 20% Zein.

Example 65 - Caffeine and glycyrrhizin in
35 a 1/1 ratio are blended together as a powder and fluid-bed coated with a solution of 25% shellac in alcohol. The coated product is agglomerated further with water and hydroxypropylmethyl cellulose (HPMC)

to obtain a product containing 30% caffeine, 30% glycyrrhizin, 25% shellac, and 15% HPMC.

Example 66 - Caffeine and sodium saccharin in a ratio of 1/1 are blended together as a powder and fluid bed coated with a solution of 25% shellac in alcohol. The coated product is agglomerated further with water and hydroxypropylmethyl cellulose (HPMC) to obtain a product containing 30% caffeine, 30% sodium saccharin, 25% shellac, and 15% HPMC.

If the blends of caffeine and other high-intensity sweeteners of examples 61-66 are tested in gum formulations such as those noted in Tables 4, 5, 6 and 7, a significant delayed release of the sweetener and reduced caffeine bitterness would be expected. This delayed release would improve the quality of flavor. The following are examples of fiber extruded PVAC/caffeine blends to give a delayed release of caffeine and give reduced bitterness:

Example 67 - Medium molecular weight PVAC and caffeine at a ratio of 3/1 are blended together as a powder and extruded. The fibers are cooled and ground to give a product containing 75% PVAC and 25% caffeine.

Example 68 - Medium molecular weight PVAC, caffeine and aspartame at a ratio of 12/4/1 are blended together as a powder and extruded, the resulting fibers are ground and give a product containing 70% PVAC, 24% caffeine and 6% aspartame.

Example 69 - Medium molecular weight PVAC, caffeine, aspartame, and sodium gluconate at a ratio of 16/4/4/1 are blended together as a powder and extruded. The fibers are ground and gives a product containing 64% PVAC, 16% caffeine, 16% sodium gluconate, and 4% aspartame.

Sodium gluconate is a bitterness inhibitor that can be mixed with caffeine before being encapsulated or entrapped. This bitterness inhibitor along with other bitterness inhibitors

such as sodium salts of chloride, ascorbic acid, glutamic acid and citric acid, as well as other various organic compounds can be added to caffeine to reduce bitterness.

5 Example 70 - A 20% hot aqueous solution of maltodextrin is mixed with a 40% hot solution of sodium gluconate. To this 2 liter mixture is added 100 grams of caffeine, dispersed and spray dried. A
10 final product containing 50% maltodextrin, 33% sodium gluconate, and 17% caffeine is obtained.

 Example 71 - A 2400 ml quantity of a 25% hot aqueous solution of maltodextrin is mixed with 50 grams of aspartame to form a suspension. To this
15 is added a hot aqueous solution of 400 grams of sodium gluconate, 200 grams of caffeine, 1200 grams of hot water. This mixture is spray dried to obtain a powder containing 48% maltodextrin, 32% sodium
gluconate, 16% caffeine, and 4% aspartame.

 Example 72 - To a 2400 gram quantity of a
20 25% hot solution of maltodextrin, 200 grams of citric acid, and 50 grams of aspartame is added and suspended. To this mixture is added a hot aqueous solution of 400 grams of sodium gluconate, 200 grams of caffeine, and 1200 grams of hot water. This
25 mixture is spray dried to obtain a powder containing 41% maltodextrin, 28% sodium gluconate, 14% caffeine, 14% citric acid, and 3% aspartame.

 The above examples are made to obtain not only a fast release of caffeine in chewing gum,
30 based on maltodextrin encapsulation, but also to obtain fast release of a sweetener and bitterness inhibitors to counteract bitter effects of caffeine.

 It should be appreciated that the methods and compositions of the present invention are
35 capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above. The invention may be embodied in other forms without departing from its spirit or essential characteristics. It

will be appreciated that the addition of some other ingredients, process steps, materials or components not specifically included will have an adverse impact on the present invention. The best mode of
5 the invention may therefore exclude ingredients, process steps, materials or components other than those listed above for inclusion or use in the invention. However, the described embodiments are to be considered in all respects only as
10 illustrative and not restrictive, and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are
15 to be embraced within their scope.

WE CLAIM:

1. A method of producing a chewing gum containing physically-modified caffeine in order to control the release rate of caffeine comprising the
5 steps of:
 - a) mixing a quantity of caffeine with a modifying agent;
 - b) drying the caffeine/modifying agent mixture; and
 - 10 c) adding a quantity of the dried material to a chewing gum formulation to provide a caffeine level in gum of from about 0.2% to about 5.0%.
2. The method of claim 1 wherein said
15 modifying agent is an encapsulating agent.
3. The method according to claim 2 wherein the caffeine and encapsulating agent are also mixed with a spray drying solvent and the resulting
20 mixture is spray dried in such a way to encapsulate the caffeine in order to increase the rate of release of caffeine in chewing gum.
4. The method of claim 3 wherein the
25 encapsulating material is selected from the group consisting of maltodextrin and gum arabic.
5. The method of claim 3 wherein the spray drying solvent is selected from the group consisting
30 of alcohol and water.

6. The method in claim 3 wherein a high-potency sweetener selected from the group consisting of aspartame, alitame, salts of acesulfame, cyclamate and its salts, saccharine and its salts, thaumatin, monellin, dihydrochalcones and combinations thereof is mixed in the drying mixture in combination with the caffeine.

10 7. A chewing gum made according to the method of claim 3.

8. The method according to claim 2 wherein the caffeine is fluid-bed coated with a solution of encapsulating agent and solvent in order to decrease the rate of release of caffeine in chewing gum.

9. The method of claim 8 wherein the solvent is selected from the group consisting of alcohol and water.

10. The method of claim 8 wherein the encapsulating material is selected from the group consisting of shellac and Zein.

25

11. The method of claim 8 wherein an additional high-potency sweetener selected from the group consisting of aspartame, alitame, salts of acesulfame, cyclamate and its salts, saccharin and its salts, thaumatin, monellin, dihydrochalcones and

combinations thereof is mixed in the drying mixture in combination with the caffeine.

12. A chewing gum made according to the method
5 of claim 8.

13. The method according to claim 2 wherein
the caffeine is encapsulated by coacervation in
order to decrease the rate of release of caffeine in
10 chewing gum.

14. The method according to claim 2 wherein
the caffeine and encapsulating agent are also mixed
with a molten material and the caffeine is
15 encapsulated by spray chilling in order to decrease
the rate of release of caffeine in chewing gum.

15. The method of claim 14 wherein the
encapsulating agent comprises wax.
20

16. The method according to claim 2 wherein
the caffeine and encapsulating agent are also mixed
with a polymer and the resulting mixture is extruded
into fine fibers in such a way as to encapsulate the
25 caffeine in order to decrease the rate of release of
caffeine in chewing gum.

17. The method of claim 16 wherein the
polymers are selected from the group consisting of
30 PVAC, hydroxypropyl cellulose, polyethylene and
plastic polymers.

18. A method of producing a chewing gum containing physically-modified caffeine in order to control the release rate of caffeine comprising the
5 steps of:

- a) mixing a quantity of caffeine with an agglomerating agent and a solvent to partially coat the caffeine;
- b) removing the solvent from the mixture of
10 caffeine and agglomerating agent to form a dried material; and
- c) adding a quantity of the dried material to a chewing gum formulation to provide a caffeine level in gum of from about 0.2% to about 5.0%.

15

19. The method of claim 18 wherein the level of coating on the agglomerated caffeine is at least about 5%.

20 20. The method of claim 18 wherein the level of coating on the agglomerated caffeine is at least about 15%.

21. The method of claim 18 wherein the level
25 of coating on the agglomerated caffeine is at least about 20%.

22. The method of claim 18 wherein the dried material is ground to a powder prior to adding the
30 dried material to the chewing gum.

23. A method of producing a chewing gum
containing a physically-modified caffeine salt
compound in order to control the release rate of the
5 caffeine salt compound comprising the steps of:

a) mixing a quantity of a caffeine salt
compound with a modifying agent;

b) drying the caffeine salt
compound/modifying agent mixture; and

10 c) adding a quantity of the dried material to
a chewing gum formulation to provide a caffeine salt
compound level in gum of from about 0.2% to about
5.0%.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/18977

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A23G 3/30

US CL :426/3, 5, 6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 426/3, 5, 6

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y | US 4,452,821 A (GERGELY) 05 June 1984 (05.06.84), see entire document. | 1-23 |
| Y | US 5,013,716 A (CHERUKURI ET AL) 07 May 1991 (07.05.91), see entire document. | 1-23 |
| Y | US 4,997,659 A (YATKA ET AL) 05 March 1991 (05.03.91), see entire document. | 1-23 |
| Y | US 4,978,537 A (SONG) 18 December 1990 (18.12.90), see entire document. | 16, 17 |
| Y | US 4,753,805 A (CHERUKURI ET AL) 28 June 1988 (28.06.88), see entire document. | 23 |



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

25 FEBRUARY 1997

Date of mailing of the international search report

25 MAR 1997

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